Bimodal Zoom

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For cochlear implanted (CI) patients speech recognition in noise still remains one of the most challenging tasks. One way to improve performance in noise is to benefit from binaural hearing (hearing with two ears). For individuals with...

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21299

Bron
Nationaal Trial Register

Aandoening

Cochlear implant, Hearing aid, Bimodal fitting, Directional microphone

Ondersteuning

Primaire sponsor: Maastricht University Medical Center (MUMC+)
Overige ondersteuning: Maastricht University Medical Center (MUMC+)
Advanced Bionics inc.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the effect of microphone configuration on speech recognition performance in noise. Two directional microphone systems will be addressed, a monaural and a binaural system, and compared to the standard omnidirectional microphone setting. The microphone systems will be tested in asymmetric configuration (same setting across ears) and/or asymmetric configuration (different setting across ears).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Cochlear implantation (CI) has become standard practice to restore hearing in severely hearing-impaired patients by providing multi-channel electrical stimulation to the auditory nerve. Although CI-patients can achieve high levels of speech recognition in quiet, speech recognition in noise still remains one of the most challenging tasks. One way to improve performance in noise is to benefit from binaural hearing (hearing with two ears). For individuals with residual contralateral hearing, a CI in one ear can be combined with an acoustic hearing aid (HA) in the other ear. This is known as bimodal hearing. For individuals without residual hearing a second CI can be an opportunity in the rare case. This is known as bilateral hearing.

A second way to improve speech recognition in noise is to improve the quality of the signal before it is offered to the ear. To that end directional microphone systems are designed as they focus on the speech signal in front and reduce the noise from other directions. Nowadays, directional microphone algorithms are available for HA’s as well as for CI’s. Both approaches (binaural hearing and directional systems) are considered complementary, however they are not yet evaluated conjointly.

Objective:

Evaluate the performance of directional microphone systems in binaural (bimodal and bilateral) cochlear implant users

Study population:

One group consists of users of a cochlear implant (CI) in one ear and a conventional hearing aid (HA) in the other ear. The other group consist users of a cochlear implant (CI) in both ears.

Study design:

A cross-over repeated measures design is carried out to single-blind evaluate the performance of directional microphone systems. During two test sessions bimodal subjects are provided with the latest speech processor for the CI ear and a state-of- the-art hearing aid in the other ear. The bilateral group will be provided with the latest CI speech processor in both ears during a single test session. Both CI and HA devices allow different microphone configurations: standard omnidirectional processing and directional multi-microphone processing in each ear separately (monaural) or combined cross ears (binaural). For each directional setting, speech perception in noise is assessed using two different masking materials (stationary noise versus fluctuating talker).

Primary study parameter:

The primary outcome is the effect of microphone

configuration on speech recognition performance in noise.

Secondary study parameters:

Secondary outcomes in this study are bimodal benefit, the

effect of masker type and listening effort. Results between

the two patient groups, bimodal versus bilateral, will be

compared.

Nature and extent of the burden and risks associated with

participation, benefit and group relatedness:

There are no known health risks associated with

participation in this study. CE-marked hearing devices (CI and HA) are used within the scope of standard care.

Participation however takes time, effort and attention from

subjects. As a result of the study subjects can be advised

towards the use of a directional microphone setting to

improve their speech recognition performance in noise.

Amendments 23-aug-2016

Doel van het onderzoek

For cochlear implanted (CI) patients speech recognition in

noise still remains one of the most challenging tasks. One

way to improve performance in noise is to benefit from

binaural hearing (hearing with two ears). For individuals

with residual contralateral hearing, a CI in one ear can be

combined with an acoustic hearing aid (HA) in the other ear,

known as bimodal hearing. For individuals without residual

hearing a second CI can be an opportunity in the rare case.

This is known as bilateral hearing.

A second way to improve speech recognition in noise is to

improve the quality of the signal before it is offered to the

ear. To that end directional microphone systems are

designed as they focus on the speech signal in front and

reduce the noise from other directions. Nowadays,

directional microphone algorithms are available for HA’s as

well as for CI’s. Both approaches (binaural hearing and

directional systems) are considered complementary, however they are not yet evaluated conjointly.

Therefore the hypothesis assessed in this study is that

directional microphone systems can improve speech

recognition performance in binaural (bimodal or bilateral)

cochlear implant users.

Onderzoeksopzet

NA

Onderzoeksproduct en/of interventie

During two test session bimodal subjects are provided with the latest speech processor for the CI ear and a state-of- the-art hearing aid in the other ear. The bilateral group will be provided with the latest CI speech processor in both ears during a single test session. Both CI and HA devices allow different microphone configurations: standard omnidirectional processing and directional multi-microphone processing in each ear separately (monaural) or combined cross ears (binaural).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Bimodal Group:
1. capacitated adult (>18 years of age)

2. patient of CI-team South-East Netherlands

3. user of a unilateral cochlear implant (CI) of the brand Advanced Bionics (AB)

4. first fit CI >= 6 months ago

5. wearing CI speech processor (almost) always (i.e. circa 10 hours a day)

6. wearing a contralateral hearing aid >50% of the time (i.e. circa 5 hours a day)

7. able to perform the speech-in-noise test (i.e. speech recognition in quiet <50%)

8. willing and able to visit hospital and participate in testing

9. agreed to participate in this study (by informed consent)

Bilateral group:
1. capacitated adult (>18 years of age)

2. patient of CI-team azM, RadboudUMC or UMCU

3. Former subject in the study NL24660.018.08/NTR1722 who completed the full fuollow-up period of four years since first implantation

4. user of a bilateral cochlear implants (CI's) of the brand Advanced Bionics (AB)

5. first fit of second CI >= 6 months ago

6. wearing CI speech processor in both ears (almost) always (i.e. circa 10 hours a day)

7. able to perform the speech-in- noise test (i.e. speech recognition in quiet >50%)
8. willing and able to visit hospital and participate in testing
9. agreed to participate in this study (by informed consent) And additionally in case of patient Radboud UMC or

UMCU:
1. Agreed to let research team inform own CI-team of participation in current study (by informed consent)
2. Agreed to let research team retrieve basic audiological information from own CI-team (by informed consent)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Bimodal group:

1. non fluent in Dutch

2.<18 years of age or incapacitated

3. bilateral cochlear implant user (CI+CI)

Bilateral group:

1. non fluent in Dutch

2. <18 years of age or incapacitated

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	24
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-11-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4696
NTR-old	NTR4901
Ander register	METC azZM/UM : 141130

Resultaten

Samenvatting resultaten
N/A